SEP - 8 2004

K041625

510(k) Summary

Submitted on behalf of:

U.S. Spinal Technologies, Inc.
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by: Elaine Duncan, M.S.M.E., RAC
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CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: **June 14, 2004**

TRADE NAME: **LTD Polyaxial Fixation System**
COMMON NAME: **spinal fixation system**

SUBSTANTIALLY EQUIVALENT TO:
The LTD, the Moss Miami system, the Xia Spine System and the Optima Spine System are all top-loading polyaxial screws with greater than 40° variability and all four systems are made from titanium. All four systems have screws that accept a 6.0mm titanium rod. All four pedicle screws use a threaded Set Screw to lock the rod to the pedicle screw. All four systems are indicated from L5-S1 for 1) Degenerative Disc Disease, 2) Spinal Stenosis, and 3) Spondylolisthesis. [The Moss Miami and the Xia Spine System are also indicated for deformities (kyphosis/scoliosis)]. However, the Moss Miami is assembled in three pieces: screw shank, bushing and head body, where as the LTD and Xia are assembled using two pieces: screw shank and head body.

DESCRIPTION of the DEVICE:
The LTD Polyaxial Fixation System consists of a variety of shapes and sizes of rods, screws and connecting components, sold with or without the surgical instrument tray. These components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The LTD Polyaxial Fixation System implant components are fabricated from medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2

INDICATIONS FOR USE:

The LTD Polyaxial Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the LTD Polyaxial Fixation System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) spinal tumor, and/or (5) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the LTD Polyaxial Fixation System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the LTD Polyaxial Fixation System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) fracture, (5) pseudarthrosis, (6) tumor resection, and/or (7) failed previous fusion.

SUMMARY of TESTING:

The LTD Polyaxial Fixation System was tested for: 1. Static axial testing in a load to failure mode in compression bending, 2. Static torsion testing in a load to failure mode in torsion, and 3. Cyclical axial compression bending testing to estimate the maximum run out load value at 5.0 x 106 cycles. The test protocol followed ASTM Standard F1717-01, "Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model." Results demonstrate that the LTD Polyaxial Fixation System complies with the recognized, voluntary performance standards for spinal implant systems. In addition, test results indicate that the LTD Polyaxial Fixation System is substantially equivalent in static and fatigue strength to predicate devices previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

U.S. Spinal Technologies, LLC.
C/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
PO Box 560
Stillwater, Minnesota 55082

Re: K041625
Trade/Device Name: LTD Polyaxial Fixation System
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3060, 21 CFR888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWQ, KWP, MNH, MNI
Dated: June 14, 2004
Received: June 15, 2004

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041625

Device Name: LTD Polyaxial Fixation System

INDICATIONS:

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Prescription Use __✓_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhouse

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041625